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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,548	10/22/1999	DAVID ROBBINS	DEX-0054	2041

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JANE MASSEY LICATA
66 E MAIN STREET
MARLTON, NJ 08053

EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

30

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/426,548

Applicant(s)

Robbins et al.

Examiner

Joseph Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 14, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2, 3, and 9 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☒ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s).
- 4) ☐ Interview Summary (PTO-413) Paper No(s).
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

This application claims benefit to provisional application 60/105,180, filed October 22, 1998.

Applicants amendment filed April 14, 2003, paper number 29, has been received and entered. Claims 2, 3 and 9 have been amended. Claims 2, 3 and 9 are pending and currently under examination.

Claim Objections

Claims 2 and 3 are objected to because they are dependent on a rejected claim. There are no other outstanding rejection over these claims, however they refer to and depend on a rejected claim.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Initially, the recitation of an 'oligonucleotide probe hybridizing' was indicated as unclear because the specific conditions for hybridization are not clearly set forth in the claim or defined in the specification. The deletion of this recitation from the claim has obviated the basis of the rejection.

Presently, claim 9 simply recites that the probe is complementary to the specific hMLH1 and hMSH2 mutants. However, these specific hMLH1 and hMSH2 mutations are defined only as single base pair changes (see page 17, lines 1-15). It is unclear if the probe encompasses a single base pair which the specification teaches to the hMLH1 and hMSH2 mutants, or if the probe comprises other characteristics not set forth in the claim. Additionally, it is noted that "complementary" is not the same as complement, and it is unclear if larger probes which hybridize or are capable of recognizing sequences which comprise the hMLH1 and hMSH2 mutants are encompassed by the claims. The amendment to the claim 9 was to delete hybridization language, so clearly the term "complementary" encompasses sequences which simply hybridize. However, the metes and bounds of the claim are unclear because the specific probe or nature of the complementary sequence of the probe is not clearly set forth in the claim. More clearly setting forth specific language directed to the specific mutations comprised is a specific MLH/MSH sequences would obviate the basis of the rejection.

Claims 2 and 3 are not included in the basis of the rejection because they more clearly set forth that binding of the probe is indicative of the presence of the specific hMLH1 and hMSH2

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mutations. In this case, the functional limitations clearly set forth definable properties of the probe set forth in claim 9.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 9 stands rejected under 35 U.S.C. 102(b) as being anticipated by Weber *et al.*

Claim 9 stands rejected under 35 U.S.C. 102(e) as being anticipated by Liskay *et al.*

With respect to claims 2 and 3, the amendment to the claims to indicate that the probe used in the screening is directed to hMLH1 mutant 1, hMSH2 mutant 1, hMSH2 mutant 2 and hMSH2 mutant 3 and that binding of the probe to the sample is indicative of the presences of hMLH1 mutant 1, hMSH2 mutant 1, hMSH2 mutant 2 and hMSH2 mutant 3, has obviated the basis of the rejection over these claims.

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With respect to claim 9, it is noted that the claim has been amended to delete hybridization language, however the claim still encompasses a sequence which is "complementary". As discussed above, complementary as known in the art and as generally supported by the specification and previous claims, encompasses sequence which are not identical but which are complementary and bind to a given sequence. With respect to the remaining mutations, because the hMLH1 and hMSH2 sequences taught by Weber *et al.* and Liskay *et al.* are complementary to the mutant sequences specifically set forth in the claim, they anticipate each of the instantly claimed probes. Furthermore, it is noted that some of the complementary sequences taught by Liskay *et al.* are associated and predictive of heredity nonpolyposis colorectal cancer (whole document and in particular figure 1, and sequences of figures 2-5, 13-16). Thus, claim 9 is anticipated by Liskay *et al.* and Weber *et al.*

Therefore, for the reasons above and of record, the rejection is maintained.

Conclusion

No claim is allowed. Claims 2 and 3 are objected to for being dependent on a rejected claim.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach


DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800